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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,997	08/29/2001	Qinwei Shi	1112-1-052CON	9957
<div>23565      7590      05/17/2007</div> <div>KLAUBER &amp; JACKSON</div> <div>411 HACKENSACK AVENUE</div> <div>HACKENSACK, NJ 07601</div>				
			<div>EXAMINER</div> <div>HINES, JANA A</div>	
			<div>ART UNIT</div> <div>1645</div>	<div>PAPER NUMBER</div>
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/941,997	<b>Applicant(s)</b> SHI ET AL.	
	<b>Examiner</b> Ja-Na Hines	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 February 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-15 is/are pending in the application.  
     4a) Of the above claim(s) 4-15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 is/are allowed.
- 6) ☒ Claim(s) 1 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No: \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Amendment Entry***

1. The amendment filed February 15, 2006 has been entered. Claims 1 and 9 have been amended. Claim 2 and 16 have been cancelled. Claims 4-8 and 10-15 have been withdrawn. Claims 1, 3 and 9 are under consideration in this office action.

***Withdrawal of Rejections***

2. The following objections and rejection have been withdrawn in view of applicants' amendments:

a) The rejection of claim 9 under 35 U.S.C. 102(b) as being anticipated by Morjana et al., (WO97/19955);

b) The rejection of claim 16 under 35 U.S.C. 102(e) as being anticipated by Potter et al., (WO97/39132);

c) The rejection of claim 16 under 35 U.S.C. 102(b) as being anticipated by Morjana et al., (WO97/19955); and

d) The rejection of claim 16 under 35 U.S.C. 112, second paragraph.

***Response to Arguments***

3. Applicant's arguments filed February 15, 2007 have been fully considered but they are not persuasive.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The new matter rejection of claim 9 under 35 U.S.C. 112, first paragraph, is maintained for reasons already of record.

Claim 9 is drawn to an isolated polypeptide consisting of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino 20 to about 30 and a C-terminus of the fragment is amino acid 95 to about 115 of native human cardiac troponin I. Neither the specification nor originally presented claims provides support for isolated polypeptide consisting of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino 20 to about 30 and a C-terminus of the fragment is amino acid 95 to about 115 of native human cardiac troponin I.

Applicant did not point to support in the specification for an isolated polypeptide consisting of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino 20 to about 30 and a C-terminus of the fragment is amino acid 95 to about 115 of native human cardiac troponin I. Applicants state that support can be found at paragraph 10, 11, 12 and 22. However paragraphs 10-12 discuss the N-terminal portion of native human cardiac troponin I consisting of about 95 to about 115 amino acids, and extending from about amino acid 20-30 to about amino acid 95-115 of native cardiac troponin I. There is no discussion of the N-terminus of the fragment is

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amino 20 to about 30 and a C-terminus of the fragment is amino acid 95 to about 115 of native human cardiac troponin I nor is there any disclosure C-terminus fragments at all.

Paragraph 22 states stable human cardiac troponin I fragments comprising an N-terminal sequence of about 95 to 115 amino acids. Degradation also cleaves 20-30 amino acids from the N-terminus, producing a fragment of about 65 to 95 amino acids in length. As used herein, the term polypeptide, marker or fragment used in the singular refers to an amino acid sequence corresponding to the N-terminal portion of human cardiac troponin I extending from the native N-terminus to about 95 to about 115 amino acids and that with the 20-30 N-terminal amino acids absent. There is no disclosure of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino 20 to about 30 . There is no disclosure of a C-terminus fragment. Neither the specification nor originally presented claims provides support for isolated polypeptide consisting of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino 20 to about 30 and a C-terminus of the fragment is amino acid 95 to about 115 of native human cardiac troponin I.

Moreover, applicant failed to specifically point to the identity or provide structural characteristics of an isolated polypeptide consisting of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino 20 to about 30 and a C-terminus of the fragment is amino acid 95 to about 115 of native human cardiac troponin I. There appears to be no teaching of that isolated polypeptide within the instant specification or originally filed claims for support of the amendment; thus it appears that the entire specification appears to fail to recite support for the newly recited isolated

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polypeptide. Applicants must specifically point to page and line number support for the identity an isolated polypeptide isolated polypeptide consisting of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino 20 to about 30 and a C-terminus of the fragment is amino acid 95 to about 115 of native human cardiac troponin I. Therefore, contrary to applicants assertions, the claim incorporates new matter and the rejected is maintained.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. The rejection of claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 1 is unclear. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a

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required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, the claim is drawn to a fragment of troponin I having 95 to 115 amino acids wherein SEQ ID NO:2 comprises the N-terminal of human cardiac troponin I. SEQ ID NO:2 has 99 amino acids. Applicants amendment to remove the "about language does not clarify the claim.

It is unclear how applicants are claiming a polypeptide consisting of an N-terminal fragment, wherein the fragment is longer than SEQ ID NO:2. Claim 1 recites the broad limitation of having 95 to 115 amino acids, and the claim also recites SEQ ID NO:2 having 99 amino acids which is the narrower statement of the range/limitation.

The language of claim 1 is confusing, the wherein clause is disconnected to the rest of the claim. It is unclear how the polypeptide would comprise SEQ ID NO:2 if the polypeptide can have 95 amino acids. Thus the metes and bounds of the claim cannot be ascertained by one of ordinary skill in the art and clarification is required to overcome the rejection and the rejection is maintained.

It is suggested that claim 1 adopt language making clear what the polypeptide consist of and removing the disconnected wherein phrase. Suggested claim language is: An isolated polypeptide consisting of an N-terminus fragment of human cardiac troponin I with at least 95 amino acids of SEQ ID NO:2 and a length of 115 amino acids.

b) Claim 9 refers to amino acid 20 to 30 and amino acid 95 to 115. It is unclear if the numbers refer to length or specific residues. Therefore it is suggested that if the

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claim is drawn to residues that clarification occur by using the "amino acid residues 20 to 30," if appropriate, is used overcome the rejection.

***Allowable Subject Matter***

6. Claims 1, 3 and 9 are free of the prior art, however claims 5 and 9 remain rejected under 35 U.S.C. 112, first and/or second paragraph. The closest prior art is Morjana et al., (WO97/19955) who teach a cardiac troponin I fragment having 153 amino acids as a result of the C-terminal processing of the native cardiac troponin I molecule wherein shorter forms of this isoform can be produced by deleting a few amino acids to/from the N-terminal, C-terminal or any part of the troponin I isoform. Morjana et al., who teach human cardiac troponin I having 210 amino acids.

Morjana et al., do not teach or suggest an isolated polypeptide consisting of an N-terminus fragment of human cardiac troponin I having 95 to 115 amino acids wherein SEQ ID NO:2 comprises the N-terminus of human cardiac troponin I. Morjana et al., do not teach or suggest an isolated troponin I polypeptide consisting of SEQ ID NO:2. Morjana et al., do not teach or suggest an isolated polypeptide consisting of a fragment of human cardiac troponin I wherein an N-terminus of the fragment is amino 20 to about 30 and a C-terminus of the fragment is amino acid 95 to about 115 of native human cardiac troponin I.



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7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines  
May 10, 2007

  
JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER /